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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,941	06/23/2003	Robert E. Sosnowski	1107-3 CIP	7846

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EXAMINER

COTTON, ABIGAIL MANDA

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/601,941

Applicant(s)

SOSNOWSKI ET AL.

Examiner

Abigail M. Cotton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/23/03, 10/8/03, 11/23/04 and 5/8/06.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-53 is/are pending in the application.
- 4a) Of the above claim(s) 30-33, 35 and 37-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/8/2003.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 30-53 are pending in the application, with claims 30-33, 35 and 37-53 having been withdrawn as drawn to a non-elected invention. Accordingly, claims 34 and 36 are being examined on the merits herein.

Election/Restrictions

Applicant's election of the claims of Group III, namely claims 34 and 36, in the reply filed on May 8, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Furthermore, the Examiner notes that, as discussed in the restriction requirement mailed on April 7, 2006, Groups I-X are drawn to different compositions and methods of treating diverse conditions, and thus represent patentably distinct inventions that would pose an undue search burden should all or even just two of the inventions be required to be searched at the same time, as the inventions require searching not only for novelty and non-obviousness, but also for the enablement of the claimed methods of treatment and intended uses of the claimed compositions.

The restriction requirement is deemed proper and is made final. Claims 30-33, 35 and 37-53 are being withdrawn as drawn to a non-elected invention.

Priority

Applicant's claim of domestic priority as a continuation-in-part of U.S. Patent Application Serial No. 09/845,141 filed April 30, 2001, now U.S. Patent No. 6,583,152, is acknowledged.

However, the Examiner notes that the patented case does not provide adequate support for the claims under 35 U.S.C. 112, first paragraph. In particular, the patented case does not disclose a composition that is "for reducing the risk or progression of diabetic neuropathy," as recited in the instant claims. Accordingly, the instant claims 34 and 36 do not receive the benefit of the filing date of the earlier application, and instead are only entitled to the filing date of the instant application of June 23, 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34 and 36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for lowering homocysteine levels in the body with the claimed compositions, does not reasonably provide enablement for the *reducing the risk*

of, i.e. preventing diabetic neuropathy with the composition as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Foreman*, 230 USPQ 546 (Board of Appeals 1986) at 547, the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation that is necessary.

(1) **The Nature of the Invention:**

The invention is drawn to a composition that is for *reducing the risk* or progression of diabetic neuropathy with a composition comprising dextromethorphan, folic acid or folate, vitamin B6 and Vitamin B12, as well as embodiments having further

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ingredients. The recitation that the composition is for “reducing the risk” of diabetic neuropathy, absent any showing to the contrary, is considered to include reducing the risk to the point that diabetic neuropathy is prevented.

(2) Breadth of the Claims:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claimed invention includes reducing the risk, i.e. preventing diabetic neuropathy with the composition. The phrase “lowering the risk of” indicates a claim whereby even those normally not at risk for developing such a disorder would be prevented from ever developing the diabetic neuropathy with the composition.

(3) Guidance of the Specification:

The guidance of the specification as “lowering the risk of” or “preventing” cardiovascular disease is completely lacking. The specification does not provide any experimental results indicating prevention or lowering the risk of diabetic neuropathy, and instead teaches that components of the composition are known in the art to reduce homocysteine levels, which Applicants indicate is related to the development of diabetic neuropathy (see pages 12-13, in particular.) Applicants do not show any results that demonstrate the actual lowering of risk or prevention of diabetic neuropathy, and do not posit any model by which potential prevention or lowering of risk could be determined.

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Thus, the specification does not provide any information regarding the lowering of risk and/or complete *prevention* of diabetic neuropathy in a population, as would be required by a claim for prevention or lowering of risk for a condition.

(4) Working Examples:

As discussed in the Guidance of the Specification section above, Applicant have not shown any working examples that demonstrate the lowering of risk and/or prevention of diabetic neuropathy.

(5) State of the Art:

The state of the art regarding the *treatment* of diabetic neuropathy is well developed. However, the state of the art regarding the *reduction in risk* or *prevention* of diabetic neuropathy is underdeveloped (see for example the article entitled "Relation between Homocysteinaemia and Diabetic neuropathy in Patients with Type 2 Diabetes Mellitus" by Ambrosch et al, of record.) Ambrosch et al. describes how limited data are available on determinants of diabetic neuropathy as its pathogenesis is multifactorial (see Summary, in particular.) Thus, Ambrosch et al. teaches that a number of factors are correlated with the development of diabetic neuropathy, but the exact relationship amongst the correlative factors is unknown.

Reasonable guidance with respect to *reducing the risk of* or *preventing* diabetic neuropathy relies on quantitative analysis from defined populations that have been successfully pre-screened and are predisposed to diabetic neuropathy. This type of data might be derived from widespread genetic analysis, family histories, correlation of genetic and environmental factors, etc. The essential element towards the validation of a preventive therapeutic is the ability to test the drug on subjects monitored in advance of diabetic neuropathy onset, and *link* those results with subsequent histological confirmation of the presence or absence of diabetic neuropathy. This irrefutable link between antecedent drug and subsequent knowledge of the prevention of the disease is the essence of a valid preventive agent. As the correlation among factors contributing to diabetic neuropathy is not known, the state of the art does not provide a reasonable method of making such a predictive analysis. Further, a preventive administration also must assume that the therapeutic will be safe and tolerable for anyone susceptible to the disease.

(6) **Predictability of the Art**

The invention is directed to the *reducing the risk of*, i.e. *preventing* diabetic neuropathy *in general* with the claimed composition. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *in re Fisher*, 427 F.2d 833, 839 (1970.)

It should also be noted that one of ordinary skill in the art would recognize that it is highly unpredictable in regard to what population will experience a diabetic neuropathy and to what extent, as discussed in (5) above. In order to administer the agent to the population at large, one would need to consider the therapeutic effects, side effects and especially potential serious toxicity that may be generated by drug-drug interactions as a result of administration of the claimed compounds to a living organism (e.g., an animal.)

(7) *The Quantity of Experimentation Necessary:*

In order to practice the disclosed invention, one would need to undergo experimentation to test the claimed compositions to determine whether or not any of they are capable of reducing the risk of and/or completely preventing diabetic neuropathy, as the instant specification does not show the complete prevention thereof.

As discussed above, the specification fails to provide sufficient support for determining all individuals susceptible to diabetic neuropathy and to what extent to allow one of ordinary skill in the art to administer to a population the composition of the instant invention for the *prevention or lowering of risk* of diabetic neuropathy in general. As a result, one of ordinary skill in the art would be forced to perform an exhaustive search for the population that is susceptible to diabetic neuropathy to use the instant invention.

Genentech, 108 F.3d at 1366 states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.”

The Examiner suggests deleting the reference to “reducing the risk” in the claims. For examination purposes, the Examiner is interpreting the claims as drawn to a composition that is for reducing the progression of diabetic neuropathy.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,054,128 to Diane Wakat, issued April 25, 2000, in view of U.S. Patent No. 6,025,369 to Rosenquist et al.

Wakat teaches dietary supplements for the cardiovascular system (see abstract, in particular.) Wakat teaches that it is known that Vitamin B₁₂, Vitamin B₆ and folic acid reduce serum levels of homocysteine, high levels of which are associated with coronary heart disease (see column 4, lines 50-60, in particular.) Wakat also teaches that antioxidants such as vitamin E and beta-carotene can reduce the risk of cardiovascular disease, and can protect arterial walls as well as lower LD cholesterol levels (see column 4, lines 14-35, in particular.) Wakat further teaches that botanical compounds such as phytochemicals and bioflavonoids improve cardiac function (see column 5, lines 22-50, in particular), and that procyanidin or cyanidin protect vascular endothelial cells (see column 5, lines 50-60, in particular.) Thus, Wakat teaches that dietary supplements such as folic acid, vitamin B₆, vitamin B₁₂, vitamin E, beta-carotene, procyanidins and flavanoids, contribute to cardiovascular health.

Wakat does not specifically teach dextromethorphan, as recited in the claims.

Rosenquist et al. teaches that NMDA receptor antagonists can be used to treat and prevent atherosclerosis, which is the principle cause of cardiovascular disease (see abstract and column 1, lines 28-45, in particular.) Rosenquist et al. teaches that examples of suitable NMDA receptor antagonists include dextromethorphan, which is an orally available drug (see column 10, lines 30-50, and column 13, lines 5-35, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to combine the dextromethorphan of Rosenquist et al. with the folic acid, vitamin B₆, vitamin B₁₂, vitamin E, beta-carotene and flavanoids/procyanidins of Wakat, and in the recited amounts, to form a composition having the ingredients, because Wakat teaches that each of the individual ingredients promotes and protects cardiovascular health, while Rosenquist et al. teaches that dextromethorphan prevents or treats atherosclerosis, which is a primary cause of cardiovascular disease. Thus, one of ordinary skill in the art would have been motivated to combine the ingredients into a single composition with the expectation of providing a composition capable of promoting cardiovascular health. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

It is respectfully pointed out that the recitation "composition for reducing the risk or progression of diabetic neuropathy" in claim 34 has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to

stand alone. See *in re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152 88 USPQ 478, 481 (CCPA 1951.)

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,054,128 to Diane Wakat, issued April 25, 2000, in view of U.S. Patent No. 6,025,369 to Rosenquist et al, issued February 15, 2000, and further in view of the article entitled "Plasma Homocyst(e)ine: A Risk Factor for Arterial Occlusive Diseases" by M.R. Malinow, 1996, the Journal of Nutrition, 124 42, pages 1238S-1243S.

Wakat and Rosenquist et al. are applied as discussed above, and teach a composition comprising dextromethorphan, folic acid, vitamin B₆, and vitamin B₁₂, that promotes cardiovascular health.

Wakat and Rosenquist et al. do not specifically teach the composition comprising betaine, as recited in the claim.

Malinow teaches the plasma homocysteine concentrations are a risk factor in coronary arterial occlusive diseases, and can be decreased by supplements such as folate or folic acid that can be provided with betaine (trimethylglycine) (see abstract and page 1242S, in particular.) Thus, Malinow teaches that trimethylglycine can be provided to reduce the risk of coronary arterial occlusive diseases, and especially in

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combination with folate or folic acid, and thus teaches promoting cardiovascular health with the administration of the trimethylglycine.

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to combine the trimethylglycine of Malinow with the folic acid, vitamin B₆, vitamin B₁₂ and dextromethorphan Wakat, and Rosenquist et al, to form a composition having the ingredients, because Wakat and Rosenquist et al. teach that each of the individual ingredients promotes and protects cardiovascular health, while Malinow teaches that trimethylglycine (betaine) reduces homocysteine levels, which are a risk factor for coronary arterial occlusive disease, and particularly in combination with folic acid or folate, such as is taught by Wakat. Thus, one of ordinary skill in the art would have been motivated to combine the ingredients into a single composition with the expectation of providing a composition capable of promoting cardiovascular health. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

It is respectfully pointed out that the recitation "composition for reducing the risk or progression of diabetic neuropathy" in claim 36 has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded

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any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *in re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152 88 USPQ 478, 481 (CCPA 1951.)

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 34 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,583,152 to

Sosnowski et al, issued June 24, 2003. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims recite a composition for lowering homocysteine levels that is "consisting essentially of" dextromethorphan, folic acid or folate, vitamin B6 and vitamin B12, whereas the instant claim is to a composition for reducing the progression of diabetic neuropathy that is "comprising" the ingredients. As the intended uses recited in the preambles are not given patentable weight, and the transitional phrase "comprising" is open transitional language, it is considered that one of ordinary skill in the art would have found it obvious to provide the instantly claimed composition over that of the patented claims. Accordingly, claim 34 is unpatentable over claims 1-5 of U.S. Patent No. 6,583,152 to Sosnowski et al.

Claim 36 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,583,152 to Sosnowski et al, issued June 24, 2003, in view of the article entitled "Plasma Homocyst(e)ine: A Risk Factor for Arterial Occlusive Diseases" by M.R. Malinow, 1996, the Journal of Nutrition, 124 42, pages 1238S-1243S, as discussed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims recite a composition for lowering homocysteine levels that is "consisting essentially of" dextromethorphan, folic acid or folate, vitamin B6 and vitamin B12, whereas the instant claims are to a composition for reducing the progression of diabetic neuropathy that is "comprising" the ingredients. As the intended

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uses recited in the preambles are not given patentable weight, and the transitional phrase "comprising" is open transitional language, it is considered that one of ordinary skill in the art would have found it obvious to provide the instantly claimed composition over that of the patented claims. Furthermore, although the patented claims do not recite betaine, the article by Malinow teaches that it is known to provide betaine to lower plasma homocysteine levels, as discussed above, and thus one of ordinary skill in the art would have been motivated to provide the betaine of Malinow in the claimed homocysteine level lowering composition with the expectation of providing a composition capable of lowering homocysteine levels. Accordingly, claim 36 is unpatentable over claims 1-5 of U.S. Patent No. 6,583,152 to Sosnowski et al in view of Malinow.

Claims 34 and 36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 30-31 of U.S. Patent Application Serial No. 10/601,942. Although the conflicting claims are not identical, they are not patentably distinct from each other because the conflicting claims recite a composition for reducing the progression of cardiovascular disease by lowering homocysteine levels that is "consisting essentially of" dextromethorphan, folic acid or folate, vitamin B6 and vitamin B12, with further claims including betaine (trimethylglycine) whereas the instant claim is to a composition for reducing the progression of diabetic neuropathy that is "comprising" the ingredients. As the intended uses recited in the preambles are not given patentable weight, and the transitional

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phrase "comprising" is open transitional language, it is considered that one of ordinary skill in the art would have found it obvious to provide the instantly claimed composition over that claimed in the conflicting application. Accordingly, claims 34 and 36 are unpatentable over claims over claims 1-6 and 30-31 of U.S. Patent Application Serial No. 10/601,942.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 34 and 36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-12 of U.S. Patent Application Serial No. 10/601,940. Although the conflicting claims are not identical, they are not patentably distinct from each other because the conflicting claims recite a method for reducing the progression of cardiovascular disease by administering a "composition" comprising dextromethorphan, folic acid or folate, vitamin B6 and vitamin B12, with further claims including betaine (trimethylglycine) whereas the instant claim is to a composition for reducing the progression of diabetic neuropathy comprising the ingredients. As the intended use of treating diabetic neuropathy recited in the preamble of the instant claims are not given patentable weight, it is considered that one of ordinary skill in the art would have found it obvious to provide the instantly claimed composition over that claimed in the conflicting application. Accordingly, claims 34 and

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36 are unpatentable over claims over claims 7-12 of U.S. Patent Application Serial No. 10/601,940.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 00/25764 to Buchholz et al. teaches a composition for treating cardiovascular disease comprising bioflavanoids (see abstract, in particular.) Also, U.S. Patent No. 5,925,634 to John W. Olney, issued July 20, 1999, teaches that it is known that NMDA receptor antagonists are capable of treating neuropathic pain, including neuropathic pain cause by pathological changes associated with diabetes (diabetic neuropathy) (see abstract and column 11, lines 40-65, in particular.)

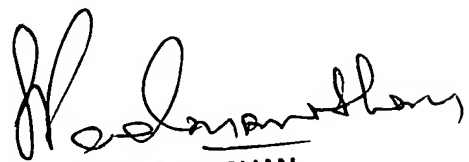
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER